Docket No.: 48317USA3C.014

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

DANIEL A. JAPUNTICH ET AL.

Serial No.: 08/240,877

Filed: May 11, 1994

For: Unidirectional Fluid Valve

Group Art Unit: 3761

Examiner: A. Lewis

AFFIDAVIT OF DAVID M. CASTIGLIONE

I, David M. Castiglione, swear as follows:

- 1. That I am presently a product development engineer at 3M Company in St. Paul, Minnesota.
- 2. That I received a Bachelor of Science degree in Materials Engineering from the Rensselaer Polytechnic Institute, which I received this degree in May of 1990. I also have a Masters of Science degree in Materials from the University of California at Santa Barbara. I received this degree in 1992.
- 3. That I began work at the 3M Company in St. Paul, Minnesota after receiving my Masters of Science degree from the University of California. I began work with 3M in the Automotive Engineered Systems Division and worked in that division through September of 1993.
- 4. That I began work for the Occupational Health & Environmental Safety Division (OH&ES) in October of 1993 and continue to work in that division at the present time. My work with the OH&ES division has entailed the design and development of respirators and respirator components. I have also worked with the study and maintenance of exhalation valves for negative pressure respirators. These duties have included evaluating the performance of exhalation valves as well as their function. I have calculated the percent flow through the valve,

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as well as analyzing the dynamic performance of the valve during simulated exhalation flows. I have also analyzed competitive designs of exhalation valves for negative pressure respirators.

- 5. That I have filed six United States patent applications for the OH&ES Division since I began employment with this business unit. The six patent applications include three utility patent applications and three design patent applications.
- 6. That I have reviewed U.S. Patent Application Serial No. 08/240,877 and the claims that are presently pending in this application. That I understand that the application claims a filtering face mask that comprises a mask body and an exhalation valve. I further understand that the exhalation valve includes a valve seat and a single flexible flap. The single flexible flap has a fixed portion and one free portion. The one free portion of the flexible flap is pressed towards the seal surface of the valve seat in an abutting relationship with it when the wearer is neither inhaling nor exhaling.
- 7. That I have reviewed UK Patent Application GB 2072516A. This patent discloses a respiratory face mask in the form of a pouch (1, 2) that is shaped to cover the nose and mouth of a wearer. The pouch is formed from a filtration effective sheet material and is provided with unidirectional exhalation valves (12, 13, 14). In Figure 2, a flap valve 13 is shown that comprises a flexible circular flap member 15 that is arranged to cover and close valve openings 16 during an inhalation. Flap member 15 flexes away from these openings 16 during an exhalation.
- 8. That I have reviewed the Office Action mailed November 8, 2000, and understand that the Examiner has taken the position that the free portion of the flexible flap disclosed in Figure 2 is "pressed toward the seal surface in an abutting relationship therewith when the wearer is neither inhaling or exhaling."
- 9. That I do not agree with the position taken by the Examiner at the bottom of page 3 of the Office Action. My review of the '516 UK patent application leads me to the conclusion that the valve 13 shown in Figure 2 does not have its flap 15 pressed towards the seal surface in an abutting relationship when the wearer is neither inhaling or exhaling. The '516 application reveals two distinctly different valves: a flap valve 13 as shown in Figure 2; and a diaphragm valve 14 as shown in Figure 3. These flaps have distinctly different constructions and operate differently. The valve shown in Figure 2 has a flat seal surface. The mounting of the flap 15 to

the seal surface at the top or fixed portion of the flap does not show a preload on the flap 15. There is nothing that can be discerned from Figure 2 or from the specification that would indicate that the flap is pressed towards the seal surface in its neutral position. And because Figure 3 shows a flap 18 resting upon the seal surface in the flap's neutral position while Figure 2 shows the flap 15 dangling away from the seal surface in an apparent neutral position also, it can be concluded that the valve 13 of Figure 2 would only become pressed against the seal surface during an inhalation. A review of the '516 UK application thus leads me to believe that the valve shown in Figure 2 is a unidirectional exhalation valve that prevents the influx of contaminants through the exhalation valve during an inhalation when it is most needed. It is not apparent to me that the valve would be pressed towards the seal surface under a neutral condition when the wearer is neither inhaling nor exhaling.

10. That I further understand that the Examiner has interpreted the '516 UK application to disclose a flexible flap that is pressed towards the seal surface because of the disclosure presented in Figure 3. This Figure, however, discloses a "button-type valve" where a flexible circular valve member 18 is centrally mounted by hub 21. This valve is different in structure and function from the valve shown in Figure 2, and therefore any teaching which shows that the flexible flap 18 engages a circular knife-edge valve seat 19 is not applicable to the flap valve presented in Figure 2.

David M. Castiglione

Subscribed and sworn to before me this ____ day of February, 2001.

Notary Public

Docket No.: 48317USA3C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

DANIEL A. JAPUNTICH ET A

Serial No.: 08/240,877

Filed: May 11, 1994

For: FILTERING FACE MASK THAT HAS A NEW

EXHALATION VALVE

Group Art Unit: 3761

Examiner: A. Lewis

AFFIDAVIT OF DAVID M. CASTIGLIONE

- I, David M. Castiglione, swear as follows:
- 1. That I am presently a product development engineer at 3M Company in St. Paul, Minnesota.
- 2. That I received a Bachelor of Science degree in Materials Engineering from the Rensselaer Polytechnic Institute. I received this degree in May of 1990. I also have a Masters of Science degree in Materials from the University of California at Santa Barbara. I received this degree in 1992.
- 3. That I began work at the 3M Company in St. Paul, Minnesota after receiving my Masters of Science degree from the University of California. I began work with 3M in the Automotive Engineered Systems Division and worked in that division through September of 1993.
- 4. That I began work for the Occupational Health & Environmental Safety Division (OH&ES) in October of 1993 and continue to work in that division at the present time. My work with the OH&ES division has entailed the design and development of respirators and respirator components. That I have filed five United States patent applications for the OH&ES Division since I began employment with this business unit. The five patent applications include three utility patent applications and two design patent applications.

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- 5. That I am familiar with U.S. Patent Application Serial No. 08/240,877 filed May 11, 1994. I have read the specification and claims in this patent application and also have read the Decision of the Board of Patent Appeals and Interferences' Decision on Appeal mailed September 14, 1999.
- 6. That I understand that the Board has held that subject matter of independent claims 18 and 24 to be unpatentable based on the disclosures in U.S. patents 2,320,770 to Cover and 3,191,618 to McKim. I further understand that the Board has concluded "that it would have been further obvious to one of ordinary skill in the art at the time the invention was made to have modified Cover's valve 46 to be attached to the modified valve seat outside a region encompassed by a single opening/orifice as suggested by the teachings of McKim to permit the valve seat to quickly, effectively, and without bounce after each opening thereof (sic)."
- 7. That I have read U.S. Patents 2,320,770 and 3,191,618, and I do not believe that the combination of Cover and McKim would have led a person of ordinary skill in the art to the present invention because the McKim patent is not pertinent to the subject matter sought to be patented in U.S. Patent Application Serial No. 08/240,877. Nor do I believe that the McKim disclosure is pertinent to the subject matter described in Cover. I do not believe that the McKim patent satisfies the legal criteria for being art analogous to the invention claimed in U.S. Patent Application Serial No. 08/240,877.
- 8. That my review of the McKim patent shows a curved seat reed valve that is designed for use in a high-speed engine, which would turn at speeds as high as 10,000 or 12,000 revolutions per minute. The reed valve described in McKim is particularly suited for a high speed operation where opening and closing forces are large. These forces can cause the valve to bounce (an elastic recoil from impact). The stated goals in McKim are full rapid opening, quick and complete closing, and eliminating float and bounce. The curved seat reed valve described in McKim is an intake valve for a two-stroke engine. The valve operates when the piston in the engine's cylinder moves from a top dead center to a bottom dead center, and the pressure within the crankcase is reduced below atmospheric pressure to overcome the spring bias of the valve reed. The valve then opens and remains open until the difference in these pressures is reduced sufficiently to allow the spring bias of the reed to return to its seat.

- 9. That the subject matter of the '877 invention, as I understand it, pertains to a filtering face mask that has a mask body adapted to fit over the nose and mouth of a person and also includes an exhalation valve that is attached to the mask body. The exhalation valve comprises a valve seat that has an orifice through which a fluid can pass and that has a seal ridge that circumscribes the orifice and has a concave curvature when viewed from a side elevation. The flexible flap has a first portion that is attached to the valve seat outside a region encompassed by the orifice. A second portion of the flexible flap assumes a concave curvature of the seal ridge when the valve is in a closed position and is free to be lifted from the seal ridge when a fluid is passing through the orifice.
- 10. That the field of the '877 invention pertains to a filtering face mask that employs an exhalation valve. A filtering face mask is worn over the nose and mouth of a person for filtering contaminants that may be present in the ambient air. Filtering face masks commonly employ exhalation valves to allow more moist exhaled air to be rapidly purged from the mask interior. The exhalation valves are used to improve wearer comfort. These valves operate at normal room temperatures and low pressures. The field of endeavor for a filtering face mask is very different from the field of endeavor of a curved seat reed valve that is used in a high-speed engine. Persons of ordinary skill in the field of designing filtering face masks do not consult documents that describe valves for gasoline engines in developing respiratory products. Exhalation valves for respirators operate under very different conditions from valves that are used in gasoline engines and require extraordinarily different design parameters.
- 11. That in exhalation valves for filtering face masks, the speed of opening is not a primary design parameter. There is no incumbent need to rapidly fill or exhaust a combustion chamber. Further, at the airflows and pressure drops that are encountered in a respiratory mask, "bounce" is not an occurring event. Investigators in the exhalation valve art for filtering face masks seek to produce exhaust valves that minimize force to open from the normally closed position. This particular design parameter is not compatible with fast-closing valves that require high forces for rapidly opening and closing. The flow volumes and flap stiffnesses are orders of magnitude higher for valves used in combustion engines as opposed to valves that are used on respiratory masks. For these reasons, a person of ordinary skill in the filtering face mask art

would not have found the McKim patent to be reasonably pertinent to the problems that are encountered in the development of an exhalation valve for a filtering face mask.

- 12. That the curved seat reed valve described in the McKim patent does not have the same purposes as the exhalation valve that is used in the present invention and that the McKim reed valve does not relate to the same problem that has been encountered in designing the filtering face mask of U.S. Patent Application 08/240,877. The reed valve described in the McKim patent is too remote to be pertinent to the subject matter sought to be patented in U.S. Patent Application 08/240,877.
- 13. That U.S. Patent 2,320,770 to Cover describes a respirator, which is designed to be worn by a person for purposes of preventing the wearer from inhaling airborne contaminants. The reed valve described in McKim would not be applied to the Cover respirator for the reasons recited above, particularly because a person of ordinary skill in the respirator art would not consult a document pertaining to a valve for a high speed gasoline engine when looking to modify a respirator or an exhalation valve for a respirator.

David M. Castiglione

Subscribed and sworn to before me this ______ day of November, 1999.

Notary Public

RENEE A. JOHNSON NOTARY PUBLIC - MINNESOTA RAMSEY COUNTY My Comm. Expires Jan. 31, 2000